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UNCLAS OSLO 000207

SIPDIS

SENSITIVE

STATE FOR EUR/NB RDALLAND, EB/IPE CARRIE LACROSSE
COMMERCE FOR 4212 MAC/EUR/OEURA
STATE PLEASE PASS TO USTR JENNIFER CHOE-GROVES AND
JASON BUNTIN
COMMERCE PLEASE PASS TO USPTO FOR JOELLEN URBAN

E.O. 12958: N/A
TAGS: ETRD KIPR ECON NO
SUBJECT: SPECIAL 301 REVIEW FOR NORWAY: PHARMACEUTICALS

REF: STATE 14937

Summary

¶1. (SBU) Post has assessed and agrees with the pharmaceutical industry's concerns about weak patent protections for many branded drugs in Norway (per the trade group "PhRMA's" Special 301 report). Post has consulted frequently with U.S. pharmaceutical firm representatives in Oslo on the issue and, at their request, has occasionally engaged Norwegian officials on their behalf. The industry advocates amending the public health care system's drug reimbursement regulations to bar pharmacies from swapping copycat generic drugs for branded drugs that, under the Norwegian system, do not enjoy full patent protections. U.S. and other pharmaceutical firms have been meeting Norwegian health care system officials on the issue for months, but so far without serious progress. Post believes that PhRMA's request to include Norway on the Special 301 Watch List can be a useful tool for spurring Norwegian authorities to take action on the patent issue. Post recommends informing appropriate Norwegian officials of PhRMA's request and encouraging them to engage constructively with the industry to address its concerns, thereby offering Norway an opportunity to act on the issue before the April 30 Special 301 report publication date. Post can assess progress and, depending on developments, offer a further recommendation on Special 301 inclusion closer to the publication deadline. End summary.

Background

¶2. (SBU) Norway has been nominated by the pharmaceuticals industry trade group "PhRMA" for inclusion on the Special 301 Watch List for failure to provide adequate patent protections for pharmaceuticals. The basis for the nomination is that prior to 1992, Norway granted patent protection only to the manufacturing process for a drug's active ingredient, as opposed to the active ingredient itself. These "process" patents provide weaker protection than "real" or "product" patents in that they open the door for generic manufacturers to claim to have found a new process to produce a branded drug, hence selling the generic in the local market does not infringe the branded drug's patent.

¶3. (SBU) Post has worked closely with local representatives of U.S. pharmaceutical firms over the last nine months on the process patent issue. We agree with the substance of PhRMA's claims. The process patent problem is a serious one for U.S. pharmaceutical firms here. While Norway has granted product patents since 1992, approximately 80-85 percent of their revenues in Norway are derived from branded drugs covered only by process patents. The annual sales revenues at risk total about USD 1.25 billion.

¶4. (SBU) Norway is the only Western European nation Post is aware of that does not offer full patent protection to branded drugs sold locally (though we understand companies in Spain may face similar problems). Finland did have a similar weakness in its patent system but remedied the problem by amending its patent legislation earlier this year. In Norway, pharmaceutical companies say fixing the problem does not require changing the patent laws, but could be done fairly quickly and simply by amending the public health care system's drug reimbursement regulations to bar pharmacies from swapping or substituting copycat generics for branded drugs that have process patents.

¶5. (SBU) The "process" versus "product" patent issue

lay largely dormant until last year, when generic manufacturers began aggressively to enter the Norwegian market with generic substitutes for branded drugs. U.S. firms filed at least five patent infringement lawsuits in 2005 to stave off generic competitors. They have, with one exception so far, won preliminary injunctions to keep the generics off the market, at least temporarily. Merck lost a preliminary injunction motion to prevent market entry of a generic substitute

for a drug accounting for 20 percent of its local sales, though the particular patent at issue had other technical weaknesses and is probably not a good precedent. Merck laid off staff following the loss.

Embassy Engagement

¶6. (SBU) Post has kept in close contact with U.S. pharmaceutical firms in Oslo on the process patent issue since it first arose last spring, but at their request did not engage the Norwegian government until shortly after last September's parliamentary elections. Talks between the pharmaceutical companies and Health Ministry officials under the prior government had gone well, but had been launched too close to the elections to effect change. When time ran short before a looming change in government, the pharmaceutical companies asked Ambassador Ong to weigh in with the Minister of Trade and Industry to gain his support for a last minute resolution. The Minister told the Ambassador, however, that he could not at that point do anything that might bind the incoming government.

¶7. (SBU) The September elections brought a new, center-left coalition to power and the pharmaceutical companies were back to square one. They opened a dialogue with the new political team at the Health Ministry but failed to make real headway on a resolution. With talks showing little progress (and Merck having lost its preliminary injunction motion), the pharmaceutical firms asked the Embassy last December to weigh in again with the Ministries of Foreign Affairs and Trade to stress the international trade/investment ramifications of the patent issue, leaving technical discussions with the Health Ministry to them. The Charge d'Affaires raised the matter on December 6 with a deputy minister of foreign affairs and Ambassador Whitney, who succeeded Ambassador Ong in early January, raised the issue again with the same official on January 25. Deputy Pol/Econ Chief also raised it with working-level contacts at the Trade Ministry. Neither ministry has responded beyond the usual diplomatic courtesies.

¶8. (SBU) The dialogue in Oslo is continuing, however. The local pharmaceutical trade association will next meet Health Ministry officials on March 10, to discuss the potential financial impact of making the regulatory changes requested by industry. The Ambassador will make an introductory call on the Minister of Trade and Industry on March 17.

Strategy and Recommendations

¶9. (SBU) Post believes that including Norway on the Special 301 Watch List, by itself, does not accomplish much, and recommends against doing so without first allowing Norway an opportunity to take action on the process patent issue. Our preferred outcome is clear -- that Norwegian health authorities amend the drug reimbursement regulations as recommended by the industry. PhRMA's request can be used as a tool to spur Norwegian authorities to take action progressing towards that outcome. Post (and Washington agencies) can leverage the Special 301 request as an "action-forcing event," bringing it to the attention of appropriate Norwegian officials and requesting that health authorities work constructively with industry to address the process patent issue well before the Special 301 report's April 30 publication date. Working with local U.S. pharmaceutical company representatives, Post can continue to monitor progress (or lack thereof) and, based on developments, offer a further assessment of the advisability of including Norway on the Special 301 list as the deadline approaches.

WHITNEY